REMARKS

Claims 1-4 and 6-11 are pending in the application, with claims 8-10 being withdrawn. Claim 5 has been cancelled. Claims 1, 6 and 11 are amended herein.

Rejections under 35 U.S.C.§112, 2nd paragraph

Claim 11 has been rejected under 35 U.S.C.§112, 2nd paragraph for being unclear in the recitation of "gene". Claim 11 has been amended to replace "gene" with "nucleic acid." Withdrawal of the rejection is therefore respectfully requested.

Rejections under 35 U.S.C.§102

The Examiner rejects claims 1-3 under 35 U.S.C.§102 as being anticipated by the Murphy et al. abstract *(J. Am. Soc. Nephrol.)*. As before, the Examiner notes that Murphy et al. teaches culturing mesangial cells in high glucose. However, the Examiner newly relies on Riser et al. *(J. Am. Soc. Nephrol.)* for teaching that culturing mesangial cells with high glucose induces the mesangial cells to produce TGF-ß1. The Examiner takes the position that by culturing the cells in Murphy et al. with high glucose, the researchers were inherently also culturing the cells with TGF-ß1 even though they did not realize it.

The present invention as encompassed by amended claim 1 is directed to culturing mesangial cells in a medium in the presence of **exogenously added** transforming growth factor ß1 (TGF-ß1). As noted above, the rejection over Murphy et al. is based on the concept of anticipation by inherency, i.e. the authors of Murphy et al. had no appreciation for the fact that when they added glucose to the cells, TGF-ß1 might also be present in the cell culture because of cells might be induced to endogenously express TGF-ß1.

Because there is no disclosure or suggestion in Murphy et al. of TGF-ß1 being present in the culture media; there is clearly no disclosure or suggestion of exogenously adding TGF-ß1 to the culture media. As such, Murphy et al. fails to disclose or suggest the present invention and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C.§103

Claims 1 and 4 have been further rejected under 35 U.S.C.§103 as being obvious over Murphy et al. combined with Riser et al. As discussed above, Riser et al. is relied on for teaching that culturing mesangial cells in high glucose induces TGF-ß1 production. However, there is no disclosure in Riser et al. of adding exogenous TGF-ß1 to the culture. As such, it is not

possible to achieve the invention even if the teachings of Murphy et al. are combined with Riser et al.

Nor is there any suggestion in Riser et al. of identifying a gene which may be involved with the presentation of diabetic nephropathy by culturing mesangial cells in a medium in the presence of exogenously added transforming growth factor ß1 (TGF-ß1) and a concentration of glucose sufficient to induce differential expression of a gene susceptible to such differential expression. Indeed, Riser et al. actually suggest the opposite by teaching that the endogenously produced TGF-ß1 is undesirable and should be neutralized with an antibody. As such, the present invention is in no way suggested by the references and withdrawal of the rejection is respectfully requested.

As the above amendments and remarks address and overcome the rejections, withdrawal of the rejections and allowance of the claims are respectfully requested.

If there are any questions with regard to the present response or other issues in the application, the Examiner is requested to please contact MaryAnne Armstrong, PhD (Reg. No. 40,069) in the Washington DC area, at (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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